DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

95172

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-05-12

November 22, 2004

Peter Rutledge Reynolds, President
LAR Manufacturing L.L.C.
c/o Orthoquest, LLC
1204 Ave J
Lubbock, Texas 79401

Dear Mr. Reynolds:

During an inspection of your establishment located at 6828 Commerce Avenue, Port Richey, FL on October 1-4, 2004, an FDA Investigator determined that your firm manufactures ceramic dental brackets, which are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), [21 U.S.C. 321(h)].

The investigator documented significant violations from the Quality System (QS) Regulation, Title 21, Code of Federal Regulations (CFR), part 820. These violations cause the device(s) you manufacture to be adulterated within the meaning of Section 501(h) [21 U.S.C. 351(h)] of the Act.

The investigator noted the following violations of the QS regulations:

1. Management with executive responsibility shall establish its policy and objectives for, and commitment to, quality. Management with executive responsibility shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization as required by 21 CFR 820.20. Your firm has not established and implemented and maintained an effective quality system at all levels of your organization (FDA 483, Item #8).

2. Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system as required by 21 CFR 820.22. Your firm has not established and implemented procedures to conduct quality audits nor have you conducted quality audits to verify that your quality system is effective (FDA 483, Item #2 & 7).

3. Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action (CAPA) as required by 21 CFR 820.100(a). Your firm lacks a written CAPA procedure and there are no established requirements to verify/validate that CAPA is effective prior to implementation and not detrimental to the finished device (FDA 483, Item #6).

4. Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. All validation activities shall be documented as required by 21 CFR 820.75. Your firm failed to document the ceramic tumbling process (FDA 483, Item #3).

5. Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements as required by 21 CFR 820.50. Your firm failed to verify or visually inspect that base ceramic material meets all specifications (FDA 483, Item #1).

6. Each manufacturer shall document all training as required by 21 CFR 820.25(b). No training documents were available for review (FDA 483, Item #4).

7. Equipment calibration shall be documented to ensure that all equipment is suitable for its intended purpose(s) and is capable of producing valid results as required by 21 CFR 820.72(a). Your firm failed to document the calibration of its optical comparator or the calibration schedule, which is conducted every six months (FDA 483, Item #5).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Additionally, no premarket submissions for Class III devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps that you are still in the process of taking to correct the noted violations, including (1) the time frames within which the corrections will be completed, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

Emma Singleton
Director, Florida District

cc: John W. Birkel, General Manager
LAR Manufacturing, LLC
6828 Commerce Avenue
Port Richey, Florida 34668-6816